

REMARKS

In the Advisory Action dated March 17, 2008, the Examiner considered Applicants' arguments made in the Request for Reconsideration filed January 29, 2008, but found those arguments unpersuasive and upheld the rejections made in the Final Office Action dated November 27, 2007. In the Final Office Action dated November 27, 2007, the Examiner rejected claims 11-18 and 20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,200,200 to Veech ("Veech"); and rejected claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of U.S. Patent No. 5,383,324 to Segers et al. ("Segers").

By this Amendment, Applicants have amended claim 11 to include, among other things, the limitations of previously-presented claim 14. Applicants have also canceled claim 14. Accordingly, claims 11-13 and 15-20 are currently pending in this application. No new matter has been added by this Amendment.

Applicants respectfully traverse the Examiner's rejection of claims 11-18 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Veech. Veech does not disclose or suggest each and every element of amended claim 11, for example. As discussed in the Request for Reconsideration filed January 29, 2008, Veech does not disclose or suggest "a first predetermined volume of an aqueous sodium bicarbonate component solution, said first predetermined volume being provided in at least one of the at least first and second compartments; and a second predetermined volume of an aqueous acid component solution, said second predetermined volume being provided in at least another of the at least first and second compartments" (emphasis added), as recited in amended claim 11.

In fact, the Examiner concedes that “Veech does not teach that the particulate mixture to be an aqueous solution.” (Office Action at 6.) The Examiner, however, contends that “[i]t would have been obvious to one of ordinary skill in the art at the time of the invention that the particulate mixture could be formulated into an aqueous solution prior to being charged into the lower compartment of the container.” (Office Action at 6-7.) The Examiner further contends that “[o]ne would have been motivated to do this because by providing the particulate mixture comprising sodium bicarbonate in an aqueous solution it would make for a more uniform distribution of the particulates when the two components are mixed for use (See Office Action mailed 6/11/2007, page 7 and 8).” (Office Action at 7.) The Examiner further contends that one skilled in the art would also have been motivated to formulate particulate sodium bicarbonate into an aqueous solution because it would provide a ‘ready for conventional intravenous administration’ solution (See column 7, lines 54-55).” (Office Action at 6.) Applicants disagree and reiterate that Veech does not provide any motivation to have an aqueous sodium bicarbonate component solution in a first compartment and an aqueous acid component solution in a second compartment of the same flexible bag assembly, as recited in amended claim 11. The cited passage of Veech disclosing a “ready for conventional intravenous administration” solution clearly refers to the solution resulting from the mixing of an aqueous batch solution in one compartment and solid crystalline sodium pyruvate in another compartment. (See col. 7, lines 45-54, as discussed above.)

In order to advance prosecution, however, Applicants have amended claim 11 to recite, among other things, that “the amount of dissolved carbon dioxide in the aqueous

acid component solution is such that a partial pressure value of said carbon dioxide exhibited by said aqueous acid component solution substantially matches a partial pressure value of carbon dioxide exhibited by said aqueous sodium bicarbonate component solution.” (Emphasis added.) Applicants submit that Veech does not disclose or suggest two separate compartments in which one compartment houses an aqueous acid component solution and the other compartment houses an aqueous sodium bicarbonate solution, where “the amount of dissolved carbon dioxide in the aqueous acid component solution is such that a partial pressure value of said carbon dioxide exhibited by said aqueous acid component solution substantially matches a partial pressure value of carbon dioxide exhibited by said aqueous sodium bicarbonate component solution” (emphasis added), as recited in amended claim 11.

In the Final Office Action, the Examiner contends that regarding “the partial pressure value of carbon dioxide, the composition of Veech is the same as the composition of the claimed invention. Products of identical chemical composition cannot have mutually exclusive properties . . . [and thus] if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.” (Office Action at 4.) Applicants disagree and further submit that this contention fails to appreciate the claimed invention, and in particular, the language added to amended claim 11. Applicants submit that the balancing of the partial pressures in carbon dioxide in the aqueous acid solution and the bicarbonate solution is not disclosed or suggested in any way in Veech.

As discussed above, Veech does not even disclose the presence of an aqueous sodium bicarbonate solution. The bicarbonate in Veech is only in the particulate form,

and thus, there is no carbon dioxide in the particulate bicarbonate containing compartment, nor is there a partial pressure of carbon dioxide in that compartment. Moreover, in Veech carbon dioxide is added to the mixture of the particulate sodium bicarbonate and aqueous acid solution in order to set the pH of the mixture, whereas, in the claimed invention, a particular amount of carbon dioxide is added to the aqueous acid solution in order to balance the partial pressure of carbon dioxide in that solution and the partial pressure of carbon dioxide in the aqueous sodium bicarbonate solution. No such balancing can occur in Veech, nor is such balancing necessary, because of the lack of carbon dioxide in the particulate sodium bicarbonate compartment. In fact, one of skill in the art at the time of the invention would not have attempted using an aqueous sodium bicarbonate solution because that would result in having to solve an additional problem, i.e., finding a way to eliminate the escape or dissociation of carbon dioxide from that aqueous sodium bicarbonate solution.

Moreover, Applicants submit that the Examiner has failed to appreciate additional benefits of the claimed invention, and in particular, benefits provided by having two aqueous solutions in separate compartments of the same bag assembly for mixing to form a dialysis liquid that were not disclosed or suggested by Veech. In both example 1 and example 2 disclosed in Veech, the buffer material (e.g., sodium pyruvate or sodium bicarbonate) was in a solid or particulate form, while the material in the separate acid/electrolyte compartment was in a liquid or aqueous form. Therefore, the carbon dioxide dissolved in the aqueous solution in the acid/electrolyte compartment only serves the benefit of acidifying this aqueous solution. The carbon dioxide does not

serve the function of stabilizing the particulate sodium bicarbonate, because in the solid state, sodium bicarbonate is completely stable.

As recited in the claimed invention, however, with the loading of a particular amount of carbon dioxide in the aqueous acid component solution and the presence of an aqueous sodium bicarbonate solution in the other compartment, the carbon dioxide loaded in the acid component solution functions to achieve an equilibrium between the two aqueous solutions, wherein, as discussed above, the carbon dioxide levels in the aqueous acid component solution and aqueous sodium bicarbonation solution are equal. The carbon dioxide dissociating from the sodium bicarbonate solution does not have any reason to migrate into the aqueous acid component solution compartment to even up the carbon dioxide pressure, because the carbon dioxide pressure equilibrium has already been established before any carbon dioxide has to escape over to the aqueous acid component solution compartment. Thus, because the dissociation of carbon dioxide from the aqueous bicarbonate solution to the aqueous acid component solution is unnecessary and does not occur, the aqueous bicarbonate solution is more stable. Applicants submit that the additional benefit of having a more stable aqueous sodium bicarbonate solution, resulting from each compartment having an aqueous solution containing carbon dioxide, is another novel aspect of the claimed invention not disclosed or suggested by Veech. Accordingly, for at least the reasons discussed above, Veech does not disclose or suggest having two aqueous solutions in separate compartments of the same bag assembly for mixing to form a dialysis liquid, nor would one of skill in the art be motivated to develop such a structure based on reading Veech. In fact, the disclosed use, in Veech, of a second chamber in a two chamber bag having

only solid sodium bicarbonate actually teaches away from the flexible bag of the present invention, as recited in amended claim 11, for example. One of skill in the art at the time of the invention would not have been motivated to start with an aqueous sodium bicarbonate solution due to having to deal with carbon dioxide escaping from the aqueous solution.

Thus, for at least the reasons discussed above, amended claim 11 is allowable over Veech. Accordingly, claims 12, 13, and 15-20 are allowable at least due to their dependence from allowable amended claim 11.

Applicants also traverse the Examiner's rejection of claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of Segers. Veech in view of Segers does not disclose or suggest each and every element of claim 19. The Examiner contends that "Veech lacks the teaching of the multiple compartment flexible bags being overwrapped in a flexible gas-impermeable plastic material. This deficiency is cured by the teachings of Segers et al." (Office Action at 7.) Applicants disagree. As discussed above with respect to amended claim 11, Veech fails to disclose or suggest "a first predetermined volume of an aqueous sodium bicarbonate component solution, said first predetermined volume being provided in at least one of the at least first and second compartments; and a second predetermined volume of an aqueous acid component solution, said second predetermined volume being provided in at least another of the at least first and second compartments" (emphasis added). Veech also fails to disclose or suggest "the amount of dissolved carbon dioxide in the aqueous acid component solution is such that a partial pressure value of said carbon dioxide exhibited by said aqueous acid component solution substantially matches a partial pressure value of

carbon dioxide exhibited by said aqueous sodium bicarbonate component solution” (emphasis added), as recited in amended claim 11. Accordingly, Segers fails to overcome the above-mentioned deficiencies of Veech and amended claim 11 is allowable over these references. Therefore, claim 19 is allowable over Veech in view of Segers at least due to its dependence from allowable claim 11.

In view of the above amendments, Applicants assert that the entire application is now in condition for allowance. A timely notice of allowance is earnestly requested.

The Examiner is invited to telephone the undersigned at (202) 408-4387, should the Examiner foresee any impediment to allowance.

The Office Action may contain statements or characterizations with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 28, 2008

By: /Aaron L. Parker/
Aaron L. Parker
Reg. No. 50,785